



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-1385]

Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice entitled “Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; Availability” that appeared in the *Federal Register* of June 30, 2022. The document announced the publication of a draft guidance, the third in a series of four methodological patient-focused drug development guidance documents that describe how stakeholders (patients, researchers, medical product developers, and others) can collect and submit patient experience data and other relevant information from patients and caregivers to be used for medical product development and regulatory decision-making. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy, Planning, Legislation and International Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993-0002, 301-796-9115, email: Lisa.Granger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of Friday, June 30, 2022 (87 FR 39101), in FR Doc. 2022-13952, the following corrections are made:

1. On page 39101, in the third column in the header of the document, “Docket No. FDA-2018-N-2455” is corrected to read “Docket No. FDA-2022-D-1385.”

2. On page 39102, in first column in “Instructions,” “Docket No. FDA-2018-N-2455” is corrected to read “Docket No. FDA-2022-D-1385.”

Dated: July 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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